

In re Application of: Michal DANIELY et al
Serial No.: 10/771,440
Filed: February 5, 2004
Office Action Mailing Date: June 10, 2009

Examiner: Bradley DUFFY
Group Art Unit: 1643
Attorney Docket: 26003

In the Claims:

1-71. (Cancelled)

72. (Currently Amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

(a) staining nucleated cells of the urine sample using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou and Hematoxylin-Eosin to thereby obtain stained nucleated cells, and subsequently;

(b) imaging said stained nucleated cells resultant of step (a) so as to obtain images of said stained nucleated cells, and subsequently;

(c) identifying by said stain in said images of step (b) a single cell having a morphological abnormality which indicates that said single cell is suspicious as a associated with transitional cell carcinoma (TCC) cell, and subsequently;

(d) staining said stained nucleated cells resultant of step (a) using fluorescent *in situ* hybridization (FISH) to thereby obtain nucleated cells stained with FISH, and subsequently;

(e) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH, and subsequently;

(f) identifying by said FISH in said images of step (e) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (c) having said morphological abnormality, associated with transitional cell carcinoma, wherein said chromosomal abnormality indicates that said cell is a transitional cell carcinoma (TCC) cell;

wherein presence of said morphological abnormality and said chromosomal abnormality in the same said single cell confirms indicates that said same single cell is a transitional cell carcinoma (TCC) cancerous cell,

thereby identifying the transitional cell carcinoma cells in the urine sample.

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73. (Currently Amended) A method of diagnosing bladder cancer in a subject, the method comprising:

- (a) obtaining a urine sample from the subject;
- (b) staining nucleated cells of said urine sample using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou and Hematoxylin-Eosin to thereby obtain stained nucleated cells, and subsequently;
- (c) imaging said stained nucleated cells resultant of step (b) so as to obtain images of said stained nucleated cells, and subsequently;
- (d) identifying by said stain in said images of step (c) a single cell having a morphological abnormality which indicates that said single cell is suspicious as a associated with transitional cell carcinoma (TCC) cell, and subsequently;
- (e) staining said stained nucleated cells resultant of step (b) using fluorescent *in situ* hybridization (FISH) to thereby obtain nucleated cells stained with FISH, and subsequently
- (f) imaging said nucleated cells stained with FISH resultant of step (e) so as to obtain images of said nucleated cells stained with FISH; and subsequently;
- (g) identifying by said FISH in said images of step (f) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (d) having said morphological abnormality associated with transitional cell carcinoma, wherein said chromosomal abnormality indicates that said cell is a transitional cell carcinoma (TCC) cell, wherein presence of said morphological abnormality and said chromosomal abnormality in the same said single cell confirms indicates that said same single cell is a transitional cell carcinoma (TCC) cancerous cell;
wherein said presence of said cancerous transitional cell carcinoma cell is indicative of a positive bladder cancer diagnosis.

74-81. (Cancelled)

82. (Currently Amended) The method of claim 72, wherein the transitional cell carcinoma cells are from a associated with bladder cancer or a kidney cancer.

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83. (Previously Presented) The method of claim 72, wherein the urine sample is obtained via voided urine or catheterization.

84. (Previously Presented) The method of claim 72, wherein said imaging is effected using an automated cell imaging device capable of at least dual imaging.

85. (Previously Presented) The method of claim 73, wherein the urine sample is obtained via voided urine or catheterization.

86. (Previously Presented) The method of claim 73, wherein said imaging is effected using an automated cell imaging device capable of at least dual imaging.

87. (New) The method of claim 72, wherein said morphological abnormality is an enlarged nucleus, a high nucleus to cytoplasm (N/C) ratio, a considerable dark appearance of a cell or an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology.

88. (New) The method of claim 73, wherein said morphological abnormality is an enlarged nucleus, a high nucleus to cytoplasm (N/C) ratio, a considerable dark appearance of a cell or an irregular nuclear border as compared to a transitional epithelial cell with a normal morphology.

89. (New) The method of claim 72, wherein said chromosomal abnormality is a polyploidy of a chromosome selected from the group consisting of chromosome 3, chromosome 7 and chromosome 17.

90. (New) The method of claim 73, wherein said chromosomal abnormality is a polyploidy of a chromosome selected from the group consisting of chromosome 3, chromosome 7 and chromosome 17.

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91. (New) The method of claim 72, wherein said chromosomal abnormality is a loss of the 9p21 locus.

92. (New) The method of claim 73, wherein said chromosomal abnormality is a loss of the 9p21 locus.